Stent design:
Factors influencing radial force and flexibility

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Disclosure

Speaker name:  **Wei Liang**

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

× I do not have any potential conflict of interest
Background of PAD

PAD: 14% - 20% in adults

Aorta & Iliac A: 30%

Femoral & Pop A: 80-90%

Tibial / peroneal A: 40-50%

Harrison’s Principles of Int Med
PTA is not always perfect

Stent as a scaffold

- **PTA study (2002)**
  - 74 patients
  - 43% major dissections
  - 32% residual stenosis >30%

- **ABSOLUTE: Stent vs. PTA (2006)**
  - 104 patients, 1:1 randomization
  - 32% insufficient PTA result led to cross over to stent

- **RESILIENT: Stent vs. PTA (2008)**
  - 206 patients 2:1 randomization 40% PTA cross over to stent due to flow limiting dissections and residual stenosis

- **Pacifier: DEB vs. PTA (2011)**
  - 91 patients, 1:1 randomization
  - 21% and 35% bail out stenting due to flow limiting dissections and residual stenosis
Stents usually have to face...

Lansky, A: Angiographic Analysis of Strut Fractures in the SIROCCO Trial. TCT 2004
Outcome of SFA Stents

Fracture and Restenosis
## Outcome of SFA Stents

<table>
<thead>
<tr>
<th></th>
<th>PP in 12 months</th>
<th>Lesion Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast</td>
<td>68%</td>
<td>4.4 cm</td>
</tr>
<tr>
<td>Resilient</td>
<td>80%</td>
<td>6.2 cm</td>
</tr>
<tr>
<td>Durability</td>
<td>72%</td>
<td>9.3 cm</td>
</tr>
<tr>
<td>Astron</td>
<td>65%</td>
<td>9.9 cm</td>
</tr>
<tr>
<td>Vienna</td>
<td>68%</td>
<td>10.9 cm</td>
</tr>
</tbody>
</table>

TASC A&B
### Outcome of SFA Stents

<table>
<thead>
<tr>
<th>139 limbs</th>
<th>Patency at 12 months</th>
<th>Patency at 24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>TASC C stent</td>
<td>83%</td>
<td>80%</td>
</tr>
<tr>
<td>TASC D stent</td>
<td>54%</td>
<td>28%</td>
</tr>
</tbody>
</table>

*J Vasc Surg 2008;48:1166*
What is perfect stent?

Stent need to mimic the nature of the artery

*Catheter Cardiovasc Interv. 2009;74(5):787-98*
What is perfect stent?

- Flexibility
- Radial force
- ......
Stent Design

In Phase

Crests

Ring

Connecting Links

Cell

Out of Phase

Bar Arm Length
What is perfect stent?

- Flexibility
- Radial force
- ......
Stent design-Flexibility

- **Flexibility of the crimped stent** contributes to deliverability

- **Conformability of the expanded stent** impacts vessel wall apposition and stent scaffolding
Stent design-Flexibility

Non-Linear Link Flexibility

Weld connections ≠ flexible
Stent design - Flexibility

Fewer Connections May Result in More Flexible Stent – But Could Sacrifice Coverage
What is perfect stent?

Flexibility

Radial force

......
What is Radial Force?

- Chronic Outward Force (COF)
- Radial Resistive Force (RRF)
- Crush Resistance (CR)
What is Radial Force?

Radial force at expansion is also known as **Chronic Outward Force (COF)**.

Radial force under compression is also known as **Radial Resistive Force (RRF)**.

**Crush Resistance (CR)** is also force under compression but at a focal point.

What is Radial Force?

- Chronic Outward Force (COF)
- Radial Resistive Force (RRF)
- Crush Resistance (CR)
- Self-expanding (SE) stents oversized to vessel diameter (1-2mm)
- COF of 7mm stents at 5mm and 6mm expansion
- Higher stent oversizing means higher COF
- Similar COF as Absolute PRO (LL)
- Lower COF than Misago, EverFlex+, SMART(er) CONTROL, Lifestent Flexstar (XL)
- Pulsar may need to be post-dilated (at implantation) more frequently than some other stents as COF lower
- Depends on resistance of artery to open, due to lesion characteristics such as calcification
- In practice, also dependant on the quality/result of pre-dilatation (lesion preparation)

"LL" = Long Lengths; "XL" = eXtra Long; "+" = plus

Comparison of COF test results

Expansion: normalized radial force at d=5mm
Expansion: normalized radial force at d=6mm
These 2D images show very different design structures

- Many design parameters influence final COF
- Main factors are
  - design itself
  - strut thickness
  - strut width
  - number of connectors
  - segment length
Clinical evidence on 
High COF triggering neointimal hyperplasia


- to evaluate the impact of stent oversizing on resultant arterial wall stress concentrations and examine the concept of a “stress threshold” for neointimal hyperplasia development
- stent “oversizing” results in an exponential increase in stresses on the vessel wall (intramural)
- intramural stress injury beyond a certain threshold may cause early restenosis by triggering neointimal hyperplasia


- low, high and ultrahigh radial force stents were implanted in porcine iliac arteries
- 30 days after implantation, significant increase in intimal thickness and neointimal hyperplasia with increasing stent force
- stents should not produce stress in the vessel wall greater than the end of the transitional domain of the vessel’s stress–strain curve


- 8mm diameter SE stents implanted in Yucatan swine Ilio-femoral arteries, stent to artery ratio (oversizing) varied from ratio of 1.2 to 1.9 (7.1 – 4.7mm)
- at 6 months all stents expanded to nominal diameter (8mm)
- severe stent oversizing (>1.4) results in exuberant neointimal proliferation and luminal stenosis

Learnings from the 3D modelling and 2 animal studies:
- Stent oversizing leads to higher COF
- High COF leads to accelerated neointimal hyperplasia and thus earlier restenosis
Vessel size change at different point of SFA-POP and After knee bending

**Straightening**
- **Stent-vessel diameter range:** 5.13 – 3.31 mm
  - 4.38 mm
  - 3.31 mm
  - 3.92 mm
  - 5.13 mm

**Bending**
- **Stent-vessel diameter range:** 5.02 – 2.98 mm
  - 5.02 mm
  - 2.98 mm
  - 4.12 mm
  - 3.12 mm

**6mm Stent**

**COF change**
We need smaller difference to COF when oversizing between 1mm to 2mm

- 7mm stent in 6mm vessel (1mm oversizing), COF of Pulsar (red line) & Absolute PRO (LL) (blue line) similar
- Lifestent Flexstar (XL) (pink line) has highest COF at 1mm oversizing

- 7mm stent in 5mm vessel COF increases
  - Pulsar increases 0.04 N/mm, Lifestent Flexstar (XL) increases 0.12N/mm (3x higher)

- Oversizing Pulsar/Absolute PRO (LL) stents makes smaller difference to COF than other stents
low COF stent is sufficient to hold open the vessel at implantation and over a longer time

If Pulsar had too low chronic outward force, then we would expect to see poor technical success* at implantation, with possibly stent migration and poor patency at follow-up

- **4EVER: Technical success* = 100%
- No reported stent migrations
- Good 6m, 12m & 24m patency rates** (4EVER)

*ability to cross and stent the lesion in order to achieve residual angiographic stenosis not greater than 30% and residual stenosis less than 50% by duplex imaging

**freedom from >50% restenosis at 12 months as indicated by an independently verified duplex ultrasound peak systolic velocity ratio (PSVR) <2.5 in the target vessel

4EVER 24 month results –
high patency maintained

(Astron Pulsar treated shorter lesions than Pulsar. Click here for details)

Courtesy of Bosiers M. 4EVER:12 month data – practical implications, CIRSE 2012; 4EVER: 24 month data LINC 2014
What is Radial Force?

- Chronic Outward Force (COF)
- Radial Resistive Force (RRF)
- Crush Resistance (CR)
Once a stent is implanted, a restenotic response starts (neointimal hyperplasia)

- Over time, neointimal hyperplasia creates new “tissue mass”.
- Tissue mass grows in volume. Cannot expand externally as constrained by vessel adventitia/media, so expands in direction of lumen. Stent struts resist force pushing them inwards, neointima grows around struts and further into lumen as shown in this illustration.

Stent will resist this compression/deformation to a point = radial resistive force/crush resistance

REMINDER
Radial Resistive Force (RRF) is a force applied around the circumference of the stent eg recoil or early restenosis

Crush Resistance (CR) is a force applied at a point of the stent eg recoil or early restenosis

Comparison of RRF test results

Pulsar has

- Higher RRF than Absolute PRO (LL) at 1mm oversizing
- Lower RRF than the other test stents
- Fairly consistent RRF at 1mm or 2mm oversizing whereas all other stents are highly influenced by amount of oversizing at implantation

Source: IIB(P)71-2011
Comparison of CR test results

**Mild compression (10%)**
- Similar resistance to crush as other stents in this test

**Moderate compression (25%)**
- Less resistance to crush than other stents in this test

**High compression (50%)**
- Less resistance to crush than other stents in this test

PULSAR = Relatively strong (but not stiff) stent that resists crushing force (e.g. from restenosis/recoil) vs. other test stents
Pulsar has enough force to resist the growing neointimal mass and maintain the vessel open over time

If Pulsar had **too low** radial resistive force then Pulsar studies would report poor patency, especially when compared to other stent studies

**12 month results** – in perspective

<table>
<thead>
<tr>
<th>STUDY NAME</th>
<th>DEVICE</th>
<th>A.L.L.</th>
<th>PP</th>
<th>FTLR</th>
</tr>
</thead>
<tbody>
<tr>
<td>4EVER</td>
<td>Pulsar-18</td>
<td>10.8 cm</td>
<td>73.4%</td>
<td>85.2%</td>
</tr>
<tr>
<td>PEACE</td>
<td>Pulsar-18</td>
<td>11.2 cm</td>
<td>79.5%</td>
<td>80.8%</td>
</tr>
<tr>
<td>RESILIENT</td>
<td>Lifestent Flexstar</td>
<td>6.2 cm</td>
<td>81.3%</td>
<td>87.3%</td>
</tr>
<tr>
<td>ZILVER FLEX (PTX study)</td>
<td>Zilver Flex</td>
<td>6.3 cm</td>
<td>73.0%</td>
<td>77.0%</td>
</tr>
<tr>
<td>ZILVER PTX</td>
<td>Zilver PTX (DES)</td>
<td>6.6 cm</td>
<td>83.1%</td>
<td>90.5%</td>
</tr>
<tr>
<td>DURABILITY II</td>
<td>EverFlex</td>
<td>8.9 cm</td>
<td>77.2%</td>
<td>N/A</td>
</tr>
<tr>
<td>SUPERA</td>
<td>Supera</td>
<td>9.0 cm</td>
<td>84.7%</td>
<td>N/A</td>
</tr>
<tr>
<td>DURABILITY</td>
<td>EverFlex</td>
<td>9.6 cm</td>
<td>72.2%</td>
<td>79.1%</td>
</tr>
<tr>
<td>ABSOLUTE</td>
<td>Absolute PRO (LL)</td>
<td>10.1 cm</td>
<td>63.0%</td>
<td>N/A</td>
</tr>
</tbody>
</table>

ALL=Average Lesion Length; PP = Primary Patency; FTLR = Freedom from Target Lesion Revascularisation

4EVER 24 month results – high patency maintained

(Astron Pulsar treated shorter lesions than Pulsar. Click here for details)

![Cumulative Primary Patency Rate](image)

Primary Patency Stent

76.2% 69.7% 37.5%
p=0.377

4EVER:12 month data – practical implications, CIRSE 2012; 4EVER: 24 month data LINC 2014; Lichtenberg M CIRSE 2013

Courtesy of Bosiers M. 4EVER:12 month data – practical implications, CIRSE 2012; 4EVER: 24 month data LINC 2014; Lichtenberg M CIRSE 2013
Summary

- Stent is the key in the PAD treatment
- Different design stents have different flexibility and Radial Force, they are the key points for the stent patency and ISR
- To know the stent and choose the right one before your practice
谢谢

Thank You！
Stent design: Factors influencing radial force and flexibility

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